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| 10/687,344 | 10/15/2003 | Ivan Osorio | 011738.00149 | 7817 |

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| EXAMINER | |
|---|---|
| ASTORINO, MICHAEL C | |
| **ART UNIT** | **PAPER NUMBER** |
| 3736 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/687,344 | OSORIO ET AL. | |
| | Examiner | Art Unit | |
| | Michael C. Astorino | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *5/14/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8,11,12 and 14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 11-12, and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Examiner acknowledges the response filed May 14, 2007.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-8, 11-12, and 14-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Pless et al. US Patent Number 6,597,954 B1. (cited by Applicant)**

Pless et al. teaches:

**(See Abstract)**

> A method for controlling epilepsy and other neurological disorders by providing electrical stimulation to a patient's brain in response to detected neurological conditions. An implantable device includes a stimulation subsystem coupled to a stimulation electrode to provide responsive electrical brain stimulation in response to an event detected via an on-board processor's analysis of data received from a detection subsystem coupled to a detection electrode located in a different portion of the patient's brain.

**(Column 4, lines 63-67 and column 5, lines 1-10)**

> Accordingly, a system and method according to the invention for treating a neurological disorder such as epilepsy includes an implantable electronic device capable of detecting seizure activity and its precursors, as well as providing responsive electrical stimulation to brain tissue.
>
> The treatment methods of the present invention can be accomplished with a number of different approaches. In a typical

embodiment, an implantable neurostimulator will have at least two electrodes near or in contact with brain tissue. Those electrodes may be located in close proximity to each other on a single lead, or may be on separate leads in entirely different portions of the brain. Each electrode may be dedicated to a single purpose, either detection or stimulation, or may be switchable between detection and stimulation functions.

**(Column 9, lines 44-67 and column 10, lines 1-3)**

An epileptogenic lesion refers to a specific pathological cause of partial epilepsy, such as a stroke, tumor, sclerosis of brain tissue, or trauma, though the specific condition may not be readily apparent. An epileptogenic region (or ictal onset zone) is a theoretical (and difficult-to-bound) region of brain tissue necessary and sufficient to give rise to seizure activity. A focal functional deficit is an area of be brain that gives rise to abnormal non-epileptic or epileptic EEG activity. A spike focus is another term for the epileptic focus concept described above, though there is not necessarily a discrete focal generator of spike activity--EEG spikes may be distributed throughout the brain. An irritative zone is a brain region that generates interictal spikes, but is not necessary for seizure initiation (as the epileptogenic region is). As will be described in detail below, the hippocampus is particularly implicated in many cases of epilepsy, and it may be advantageous to sense or stimulate in the hippocampus (or other structures of the limbic system) regardless of the origin of abnormal EEG activity. Other locations in the temporal lobe, and elsewhere in the brain (including corresponding contralateral locations, even when seizures fail to generalize to the contralateral hemisphere), also present themselves as candidates for treatment in accordance with the invention. The possibilities are too numerous to set forth herein, but should be apparent to a neurosurgical or neurological practitioner having skill and experience in treating epilepsy.

**(Column 11, lines 35-53)**

The stimulation subsystem 624 is capable of applying electrical stimulation to neurological tissue through the electrodes 612-618. This can be accomplished in any of a number of different manners. For example, it may be advantageous in some circumstances to provide stimulation in the form of a substantially continuous stream of pulses. Preferably, therapeutic stimulation is provided in response to abnormal events detected by the EEG analyzer function 626 of the detection subsystem 622. As illustrated in FIG. 6, the stimulation subsystem 624 and the EEG analyzer function

626 are connected; this facilitates the ability of stimulation subsystem 624 to provide responsive stimulation as well as an ability of the detection subsystem 622 to blank the amplifiers while stimulation is being performed to minimize stimulation artifacts. It is contemplated that the parameters of the stimulation signal (e.g., frequency, duration, waveform) provided by the stimulation subsystem 624 would be specified by other subsystems in the control module 610, as will be described in further detail below.

**(Column 12, lines 35-56)**

FIG. 7 illustrates details of the detection subsystem 622 (FIG. 6). Inputs from the electrodes 612-618 are on the left, and connections to other subsystems are on the right.

Signals received from the electrodes 612-618 (as routed through the electrode interface 620) are received in an electrode selector 710. The electrode selector 710 allows the device to select which electrodes (of the electrodes 612-618) should be routed to which individual channels of the detection subsystem 622, based on control received through a control interface 718 from the memory subsystem 630 or the CPU 632 (FIG. 6). The electrode selector 710 provides signals corresponding to each selected electrode (of the electrodes 612-618) to a bank of differential amplifiers 712, which are gain-matched and adapted to amplify the input signals to a level capable of being processed by a system or method according to the invention. The bank of differential amplifiers 712 includes a plurality of channels; each channel receives a pair of electrode signals from the electrode selector 710 and amplifies the difference in potential between them to derive an analog input signal representative of the bipolar signal between two selected electrodes.

**(Column 13, lines 27-40)**

Referring initially to the input side of FIG. 6, the stimulation subsystem 624 includes a control interface 810, which receives commands, data, and other information from the CPU 632, the memory subsystem 630, and the detection subsystem 622. The control interface 810 uses the received commands, data, and other information to control a stimulation generator 812. The stimulation generator 812 is adapted to provide electrical stimulation signals appropriate for application to neurological tissue to terminate a present or predicted undesired neurological event, especially an epileptic seizure (or its precursor). As set forth above, the stimulation generator 812 is typically activated in response to

conditions detected by the detection subsystem 622, but may also provide some substantially continuous stimulation.

**(Column 14, lines 35-67 and Column 15, lines 1-59; in part below)**

The stimulation parameters (e.g., pulse width, voltage, current, frequency, etc.) would then be selected on the programmer 512 and transmitted to the control module 610 via the wireless link 510. Various commands to start and stop stimulation on specific electrodes would also be transmitted from the programmer 512 to the control module 610.

Finally, the stimulation effects on the patient would be noted by the physician as in a **standard brain mapping procedure**. This standard brain mapping procedure typically uses electrodes near the site of an epileptic focus to map brain functions as a precursor to surgical excision of the epileptogenic region, but in connection with the present invention, the analogous procedure serves as an indication of where sensing and stimulation might advantageously be performed.

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Again, after sufficient epileptiform activity has been collected by the programmer 512, a physician would use the stored EEG data, as displayed by the programmer 512, to select an appropriate set of brain electrodes for long-term sensing and stimulation by the implantable device. As illustrated in U.S. patent application Ser. No. 09/543,264 to Pless, entitled "A Neurostimulator Involving Stimulation Strategies and Process for Using It," which is hereby incorporated by reference as though set forth in full herein, the analysis performed by the physician (and automatically by the programmer 512) on the stored EEG data would be used to set parameters for epileptiform activity detection algorithms employed by,the implantable device 110 according to the invention.

Commands to start and stop electrical stimulation to the appropriate set of brain electrodes are then sent from the programmer 512 to be stored in the implantable device 110 and activated in response to a command from the physician. Stimulation is performed to induce epileptiform activity that may include after-discharges from an epileptogenic region of the patient's brain. Such after-discharges typically are similar to natural epileptiform activity. It should be noted that inducing after-discharges may require empirical testing of various stimulation parameters programmed by the programmer 512 into the

implantable device 110; this procedure may require substantial physician interaction.

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It should be noted that an automated system could be used to detect natural epileptiform activity and automatically respond, thereby testing the stimulation parameters, rather than inducing artificial epileptiform activity and responding manually, as described above. If a patient experiences seizures frequently, such as every few hours, this may be a practical approach. On the other hand, if the patient has seizures infrequently, such as a small number per week, it most likely would not be practical to proceed in this manner.

After successful stimulation parameters are identified, all such parameters, including the selected stimulation electrodes, are retained in the programmer 512 and stored in the device 110. If the device 110 has not yet been implanted, or if a different apparatus is appropriate (e.g., the substitution of an implantable device for an external device used for the test procedure set forth above), the parameters are stored in the appropriate device, which is then tested for efficacy in the automatic detection and termination of seizure activity. If any adjustments are necessary, they are made by the physician, and the device 110 is implanted (along with any necessary electrodes for detection and stimulation).

**(See also claims 7-12.)**

***Response to Arguments***

Applicant's arguments with respect to claims 1-8, 11-12, and 14-23 have been considered but are moot in view of the new ground(s) of rejection.

**The Applicant is invited to request an interview to discuss the rejection and allowability of the application.**

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Astorino whose telephone number is 571-272-4723. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Astorino

Michael Astorino
October 29, 2007